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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,776

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Kent Lee

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HOLLINGSWORTH & FUNK, LLC
8009 34TH AVE S.
SUITE 125
MINNEAPOLIS, MN 55425

EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Supplemental
Notice of Allowability**

Application No.

10/824,776

Examiner

KAREN E. TOTH

Applicant(s)

LEE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the remarks filed 20 November 2008.
2. ☒ The allowed claim(s) is/are 1-21, 23, 24, 26-53, 56-59, 61-82.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input checked="" type="checkbox"/> Other <u>Response to Rule 312 Communication (PTO-271).</u> |
|---|--|

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

DETAILED ACTION

Election/Restrictions

1. The cancellation of Claims 4-7, 10, 13-16, 39-42, 44-46, and 48-51, previously withdrawn from consideration as a result of a restriction requirement, was performed in error. Since the claims have been cancelled, they are being re-created as new claims in the following Examiner's Amendment.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Due to the cancellation of non-elected claims that was performed in error in the previous Office Action, the following new claims are being presented to replace the cancelled claims.

Claim 83 (new): The method of claim 1, wherein the disordered breathing event comprises Cheyne-Stokes respiration.

Claim 84 (new): The method of claim 1, wherein the disordered breathing event comprises periodic breathing.

Claim 85 (new): The method of claim 1, wherein the disordered breathing event comprises apnea.

Claim 86 (new): The method of claim 1, wherein the disordered breathing event comprises hypopnea.

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Claim 87 (new): The method of claim 1, wherein detecting the disordered breathing event comprises detecting the disordered breathing event based on blood gas level.

Claim 88 (new): The method of claim 1, wherein detecting the disordered breathing event comprises detecting the disordered breathing event based on cardiovascular system conditions.

Claim 89 (new): The method of claim 1, wherein detecting the disordered breathing event comprises detecting the disordered breathing event based on cardiopulmonary conditions.

Claim 90 (new): The method of claim 1, wherein detecting the disordered breathing event comprises detecting the disordered breathing event based on nervous system conditions.

Claim 91 (new): The method of claim 1, wherein detecting the disordered breathing event comprises detecting the disordered breathing event based on non-physiological conditions.

Claim 92 (new): The system of claim 37, wherein the respiration sensor comprises a microphone configured to detect snoring sounds.

Claim 93 (new): The system of claim 37, wherein the respiration sensor comprises an airflow sensor.

Claim 94 (new): The system of claim 37, wherein the respiration sensor comprises a sensor configured to sense blood gas.

Claim 95 (new): The system of claim 37, wherein the respiration sensor comprises a sensor configured to sense cardiovascular system conditions.

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Claim 96 (new): The system of claim 34, wherein the disordered breathing detector comprises a sensor configured to sense nervous system conditions.

Claim 97 (new): The system of claim 34, wherein the disordered breathing detector comprises a sensor configured to sense muscle system conditions.

Claim 98 (new): The system of claim 34, wherein the disordered breathing detector comprises a sensor configured to sense non-physiological conditions.

Claim 99 (new): The system of claim 34, wherein the motion sensor comprises a transthoracic impedance sensor.

Claim 100 (new): The system of claim 34, wherein the motion sensor comprises a respiratory band.

Claim 101 (new): The system of claim 34, wherein the motion sensor comprises a switch.

Claim 102 (new): The system of claim 34, wherein the motion sensor comprises an electromyogram sensor.

Allowable Subject Matter

3. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to anticipate or make obvious the inventions of claims 1-3, 8-12, 17-21, 23, 24, 26-33, 70-76, and 81-91, including, *inter-alia*, classifying a disordered breathing event as mixed central and obstructive disordered breathing if measured respiratory effort motion is equal to or above a certain threshold for a first portion of the event and below the threshold during a second portion of the event.

The prior art of record fails to anticipate or make obvious the inventions of claims 34-38, 43, 47, 52, 53, 56-59, 61-69, 77-79, and 92-102, including, *inter-alia*, classifying a disordered breathing event as obstructive if a motion threshold is met or exceeded during a first portion of the event, and as central if the motion signal is below a motion threshold during a second portion of the event.

Cho (US Patent 6641542) discloses classifying disordered breathing in a patient by detecting a sleep disordered breathing event (column 8, lines 46-48; step 410), sensing motion associated with respiratory effort during the event (column 6, lines 52-54, column 7, lines 19-32, 47-49, and 63-65; step 420), and classifying the event based on the sensed motion (column 6, lines 57-65; column 9, lines 16-19; step 430), where the detection, sensing, and classification are all performed implantably (figures 1 and 2; column 3, lines 14-21). Cho does not disclose using a motion threshold to compare motion associated with respiratory effort during two time periods.

Brydon (US Patent 6547743) discloses that signals indicative of both central and obstructive events may be expressed simultaneously during mixed apnea events (column 20, lines 43-46), and that a disordered breathing event would be classified as obstructive if a motion threshold is met or exceeded and as central if the threshold is not met, but does not disclose classifying portions of a single event as either of the two.

Burton (US Patent Application Publication 2007/0032733) discloses a method of classifying mixed central and obstructive disordered breathing events

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as when periods of both effort and non-effort are present in the respiration signal (paragraph [0510]).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. E. T./
Examiner, Art Unit 3735